K122686

510(k) Summary

Date of Summary: August 29, 2012

NOV 16 2012

Submitter: Roche Diabetes Care AG
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Contact Person: Catherine Green
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Device Trade Name: ACCU-CHEK® Ultraflex Infusion Set

Device Common Name: Subcutaneous infusion set

Classification name: Intravascular administration set

Regulation Number: 21 CFR 880.5440

Product Code and Class: FPA, Class II

Predicate Device K101196 ACCU-CHEK Ultraflex Infusion Set

Device Description

The ACCU-CHEK Ultraflex is an ethylene oxide sterilized, single-use, disconnectable infusion set with soft cannula perpendicular to the adhesive, for transfusion of insulin into the subcutaneous tissue. The infusion set includes a stainless steel introducer needle to facilitate insertion of the soft cannula into the dermis. The unit is designed to interface with commercially available insulin infusion pumps with suitable luer connections. The insulin infusion pump systems are designed to control the delivery of U100 insulin as prescribed by a health care professional. The system (infusion set, insulin infusion pump, and insulin) is indicated for patients with insulin dependent diabetes mellitus.

Intended Uses

The ACCU-CHEK Ultraflex is an infusion set for the subcutaneous infusion of insulin administered with microdosage insulin pumps.

Technological Characteristics

The modified ACCU-CHEK Ultraflex infusion set uses the same materials and design as the predicate device. The modified ACCU-CHEK Ultraflex infusion set provides a 6mm cannula length variant. The predicate device includes cannula lengths of 8mm and 10mm. There are no other significant differences between the modified ACCU-CHEK Ultraflex and the predicate ACCU-CHEK Ultraflex. The fundamental scientific technology, indications for use, intended use, materials, design, sterilization and packaging are identical between the proposed and predicate devices.

Dimensional characteristics of the predicate compared to the modified device are listed below.

Feature	Predicate	Modified
Cannula length	8mm,10mm	6mm, 8mm, 10mm
Tube Length	30, 60, 80, 110 cm	30, 60, 80, 110 cm
Tubing ID/OD	0.39 mm x 1.46 mm	0.39 mm x 1.46 mm
Priming Volume (average for tube set + 1 IU for priming head set)	69µl, 104µl, 128µl, 163µl	69µl, 104µl, 128µl, 163µl

Performance Standards

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.
FDA has published a guidance document for review of intravascular administration sets entitled, Guidance on Premarket Notification for Intravascular Administrations Sets. FDA has also published a guidance document for review of external infusion pumps entitled, Guidance On The Content Of Premarket Notification [510(k)] Submissions For External Infusion Pumps and a draft update entitled, Guidance for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions. FDA has published a guidance document for review of medical devices with sharps entitled, Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA. Roche has evaluated this modified device according to the recommendations provided in these guidance documents and our internal system development guidelines and standard operating procedures.

Testing Conclusions

Non-clinical testing of the modified ACCU-CHEK Ultraflex Infusion Set demonstrated that the device meets the requirements for its intended use. The data also demonstrates that the ACCU-CHEK Ultraflex Infusion Set is substantially equivalent to the predicate device. Non-clinical testing included: soft cannula length confirmation, introducer needle length confirmation, insertion force, and system functional verification testing.

Clinical testing was not required to validate the device modification or support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 16, 2012

Ms. Catherine Green
Regulatory Affairs Manager
Roche Diabetes Care AG
Kirchbergstrasse 190
Burgdorf, Switzerland CH-3401

Re: K122686
Trade/Device Name: ACCU-CHEK® Ultraflex Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 18, 2012
Received: October 19, 2012

Dear Ms. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=13000 92402

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122686

Device Name: ACCU-CHEK® Ultraflex Infusion Set

Indications For Use:

The ACCU-CHEK® Ultraflex is an infusion set for the subcutaneous infusion of insulin administered with microdosage insulin pumps.

Digitally signed by Richard C. Chapman
Date: 2012.11.16 08:33:21 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122686

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)